

explanation of how Sun et al. qualifies as a 102(b) reference for the Applicant's Claims 7-12, nor for new Claims 17-20 added in the Preliminary Amendments on October 7, 2004.

General Comments

Sun, Patent #6,273,856, uses a rate responsive pacemaker with an accelerometer or minute ventilation sensor to derive metabolic equivalents data. The data gathered from the pacemaker can be processed into forms useful for a physician, which could include maximum daily exertion levels, average daily exertion levels, moving average exertion levels, exertion level above a certain threshold, the number of times a day the exertion level is above the threshold and the duration of time above a threshold. This data enables a physician to evaluate the pacing parameters for a patient, important for a pacemaker user.

In the preferred embodiment of the '856 Sun device, the pacemaker device is coupled to a patient's heart using electrical lead assembly. Instrumentation is used, an oscillator (36), to produce an alternating circuit to produce a carrier signal amplified by a sense amplifier(38), which is then processed to establish a minute ventilation data signal, which is used for adjusting the rate of the pulse generator issues cardiac stimulating pulses to the heart. Also, an integrated silicon accelerometer (44) used to gather data, which along with the minute ventilation sensor, can be used to gather data which can be used to calculate the metabolic equivalent in the patient due to patient activity. The pacemaker with these data gathering sensors allow information to be gathered which shows the MET calculations for a patient during the day, including a daily maximum MET level. All of this is useful to a physician for setting pacing parameters of the pacemaker for the patient.

In effect, the Sun '856 reference uses a pacemaker with certain sensors implanted within the pacemaker to measure the daily activities of a patient. These measurement data may be used to establish the metabolic equivalents for the patient, which enables the physician using this data to establish proper parameters for the pacemaker to control the patient's heart rate.

In this application, Claim 7 requires a physiological stress test method. The Sun reference does not disclose a physiological stress testing method of any kind. Rather, the method for a physiological stress test of Claim 7 requires calculating a MET equivalent. The Sun '856 apparatus

can calculate a metabolic equivalent for a patient. However, Claim 7 further requires that the calculated metabolic equivalent is used to estimate a volume of oxygen value. This is not disclosed in the Sun reference. Claim 7 further requires establishing a physiological stress testing protocol, “wherein said test protocol establishes a predetermined work load that increases a predetermined level, said predetermined work load is higher when the volume of oxygen values are higher.” The Sun reference does not disclose a physiological stress testing protocol of any kind, much less one that is based on the volume of oxygen value estimated from the metabolic equivalent data. Claim 7 further requires placing a patient on an exercise apparatus that applies the predetermined work load regardless of how fast the exercise equipment is operated. The Sun reference does not disclose use of an exercise apparatus and certainly not one that applies a predetermined work load no matter how fast the exercise apparatus is operated. Claim 7 finally requires that during the stress testing protocol the physiological parameters of a patient are measured and the protocol is stopped when these parameters reach a predetermined level. Again, these limitations are simply not found in the Sun reference.

Claim 8 adds a further limitation to Claim 7 that the step of providing an exercise apparatus further includes an exercise apparatus that requires no weight bearing on the patient’s joints. Since the Sun reference does not disclose an exercise apparatus, it cannot disclose an exercise apparatus that places no weight on the patient’s joints.

Claims 9, 10, and 11 further refine how the step of providing an exercise apparatus may be used by a patient while carrying out the protocol. Since the Sun reference does not disclose any step of providing an exercise apparatus, it cannot therefore anticipate Claims 9, 10, and 11.

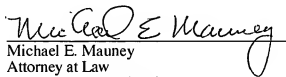
Claim 12 adds a further limitation to the step of applying a predetermined work load of sensing how fast a patient is operating the exercise apparatus and adjusting the electromagnetic resistance added in Claim 10 so that a predetermined work load is applied regardless of how fast a patient is operating the exercise. Again, because the Sun reference does not provide exercise equipment, there can be no anticipation of Claim 12 by the Sun reference.

Claims 17-20 were not addressed in the Office Action by the Examiner despite the fact they were entered prior to the date of the Office Action, nor did the Examiner refuse to enter those amendments by an action of the Commissioner. Nevertheless, the Applicant will address any rejections to Claims 17-20 based on the Sun '856 reference. Claim 17 claims a self-adjusting apparatus that applies a predetermined work load to a user no matter how fast the exercise equipment is operated in the physiological stress testing method of Claim 7. This apparatus is required to have limitations (a) to (f) which include a frame with a seat, pedals, and movable handles, a resistance apparatus that moves and responds to motion of pedals and handles, means for applying a resistance and adjusting the resistance, and means for controlling the means for adjusting. Because Sun does not provide any exercise apparatus, it cannot therefore be a 102(b) reference for Claim 17. Claims 18-20 add further limitations to the exercise apparatus of Claim 17. However, because the Sun '856 reference does not provide any exercise apparatus, Claims 18-20 will not be separately argued because, if Sun fails to be a 102(b) reference for Claim 17, necessarily it cannot be a 102(b) reference for dependant Claims 18, 19, and 20.

Conclusion

Pending Claims 7-12 were rejected by the Examiner under 102(b) based on Sun '856. The Applicant has addressed these rejections pointing out that the Sun '856 reference cannot be a 102(b) bar to Claims 7-12. The Examiner did not address Claims 17-20. Nevertheless the Applicant has shown that the Sun '856 patent is not a 102(b) reference for Claims 17-20. Consequently, it is believed that all claims currently pending in the application are in a condition for allowance and the same is respectfully requested.

This the 17 day of JAN, 2005.


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